

Figure 1

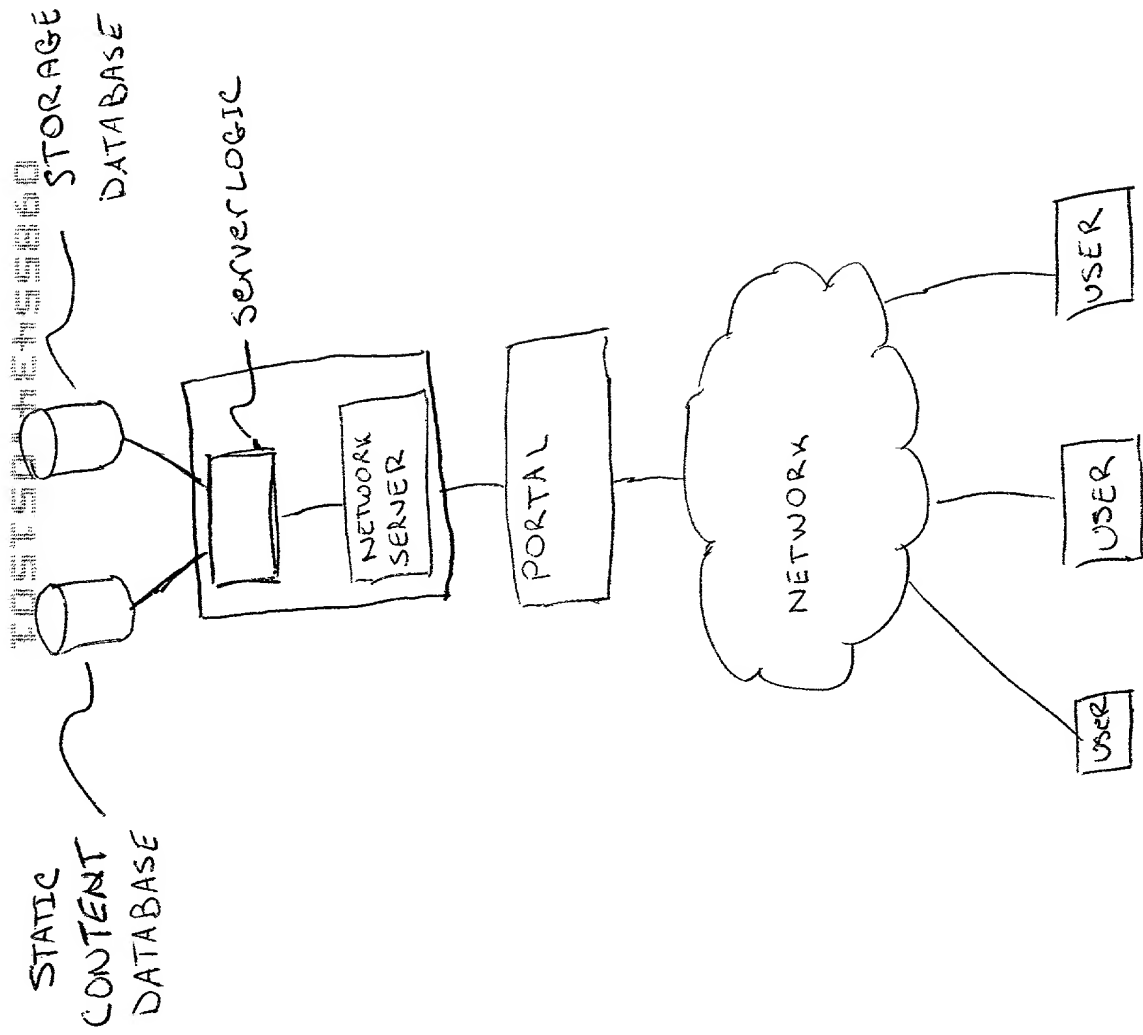
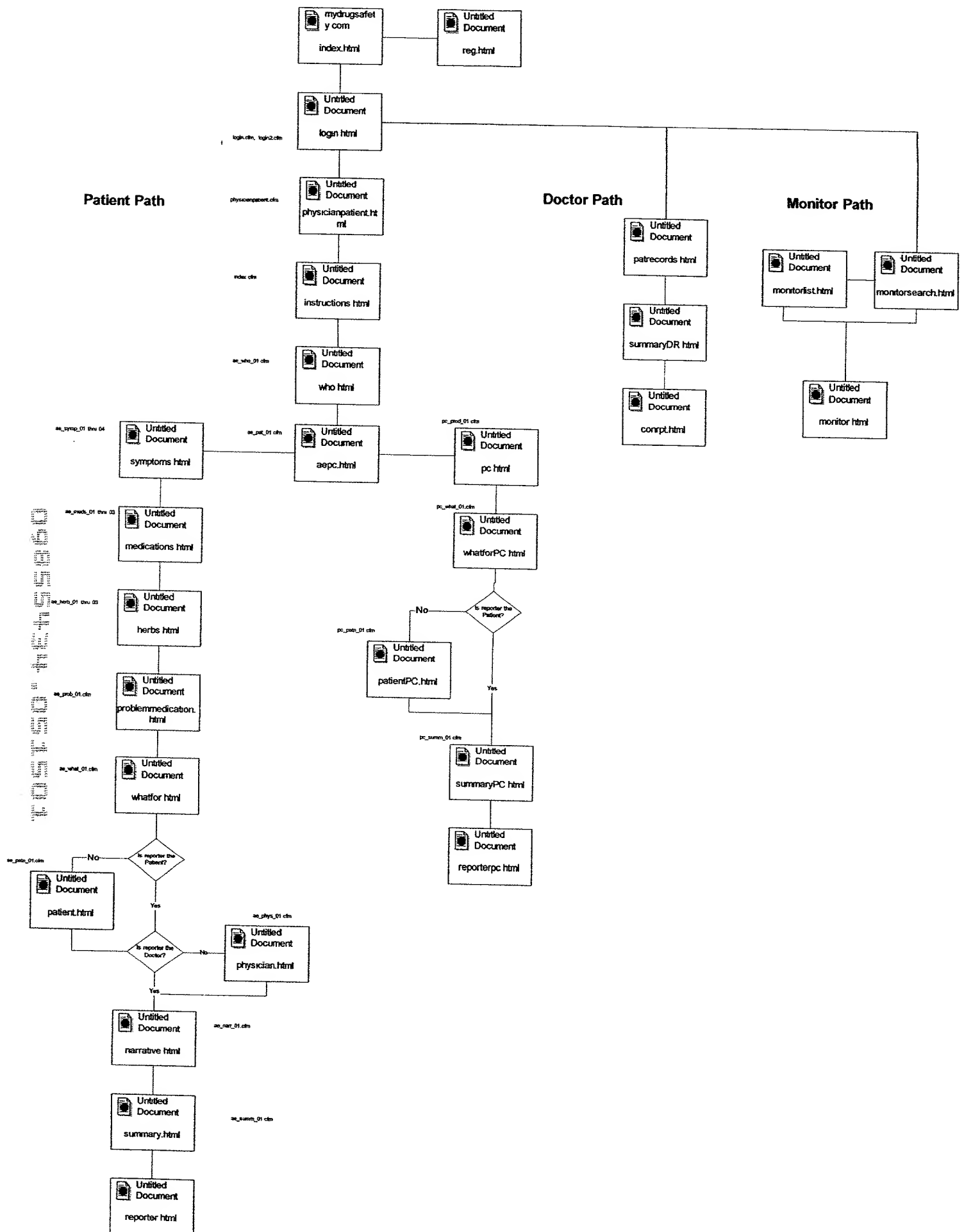


Figure 2



Portal Pilot Workflow

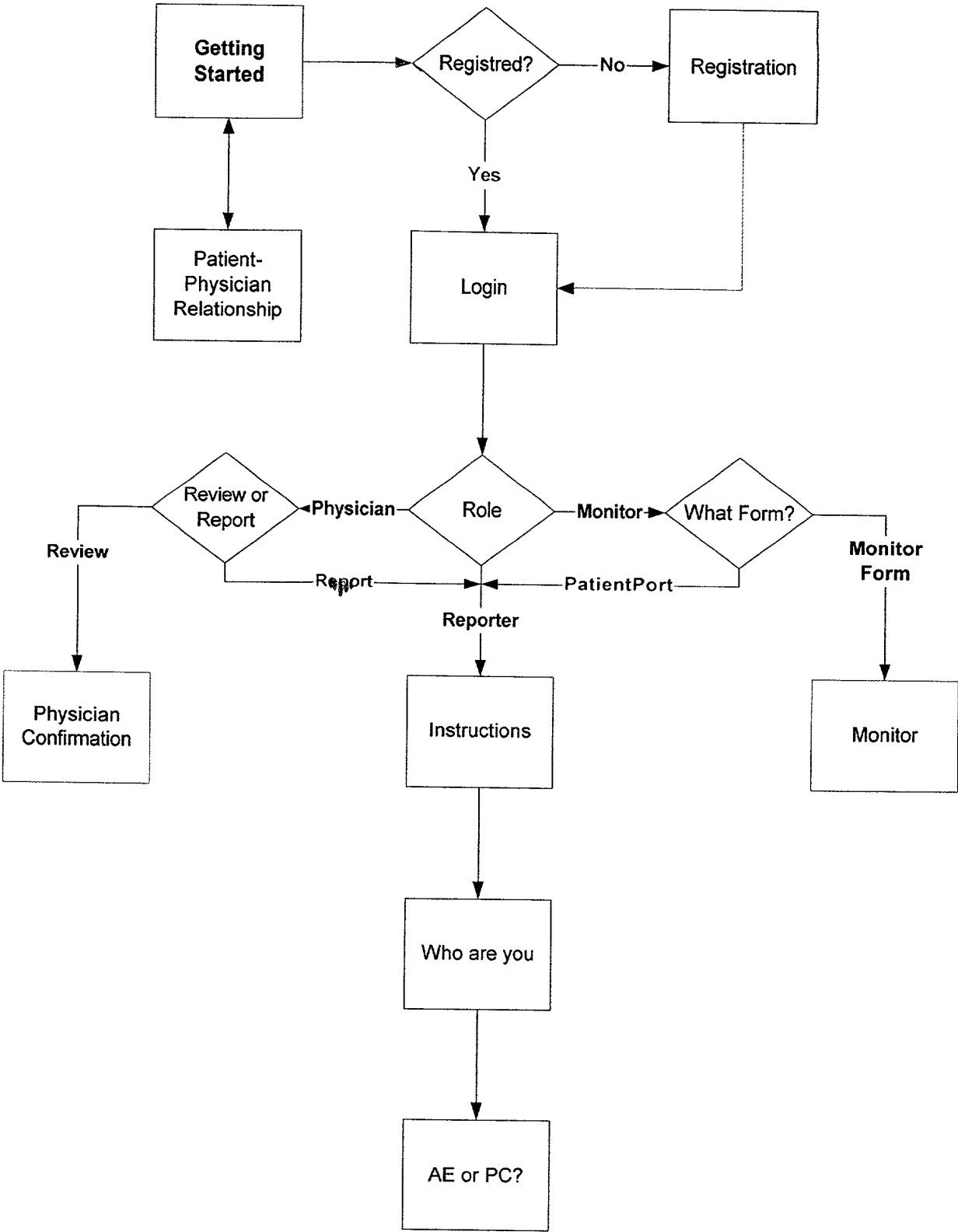


Fig 3a

AE or PC Guided Reporting

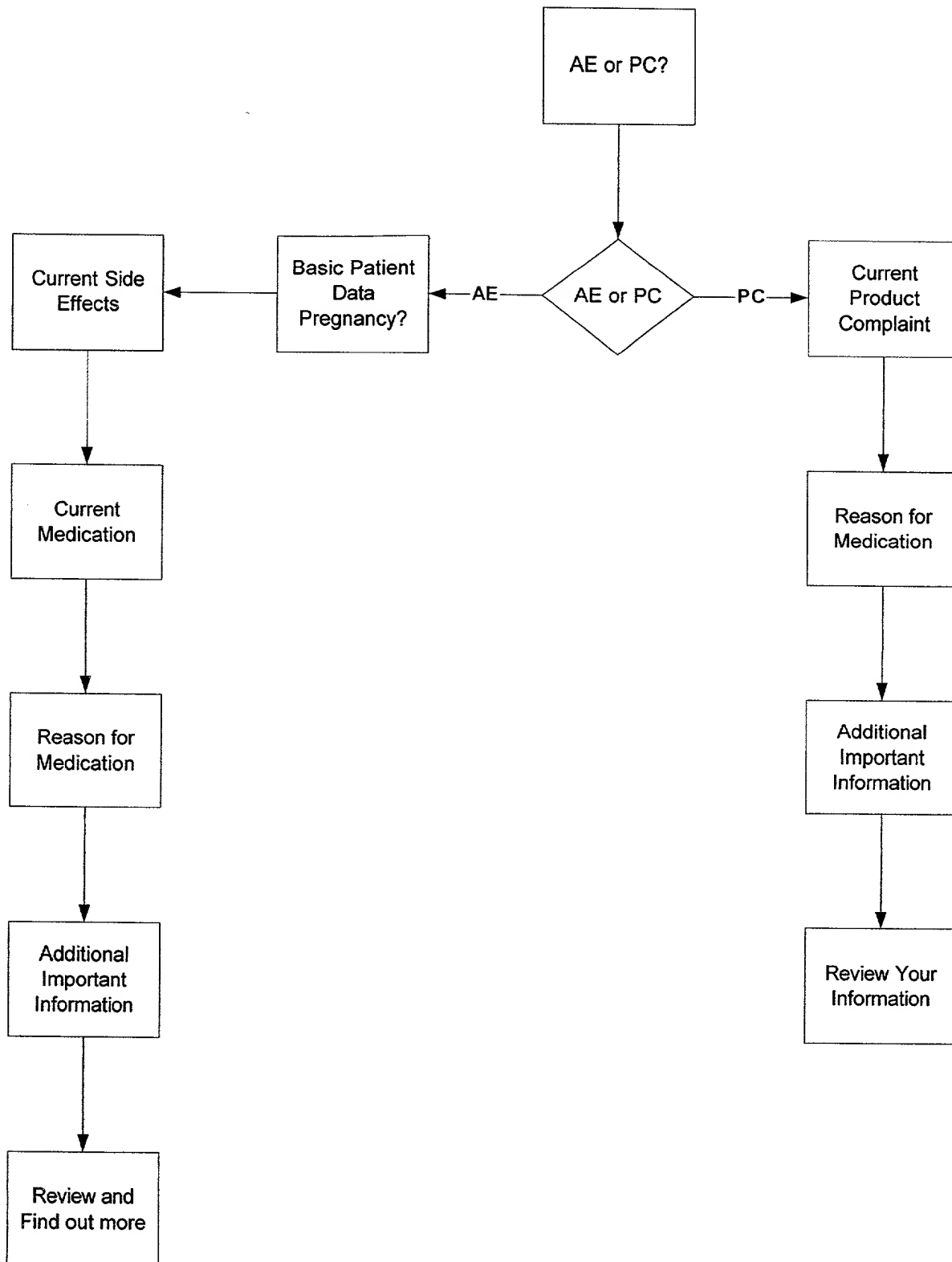


Fig 3b

Physician Confirmation

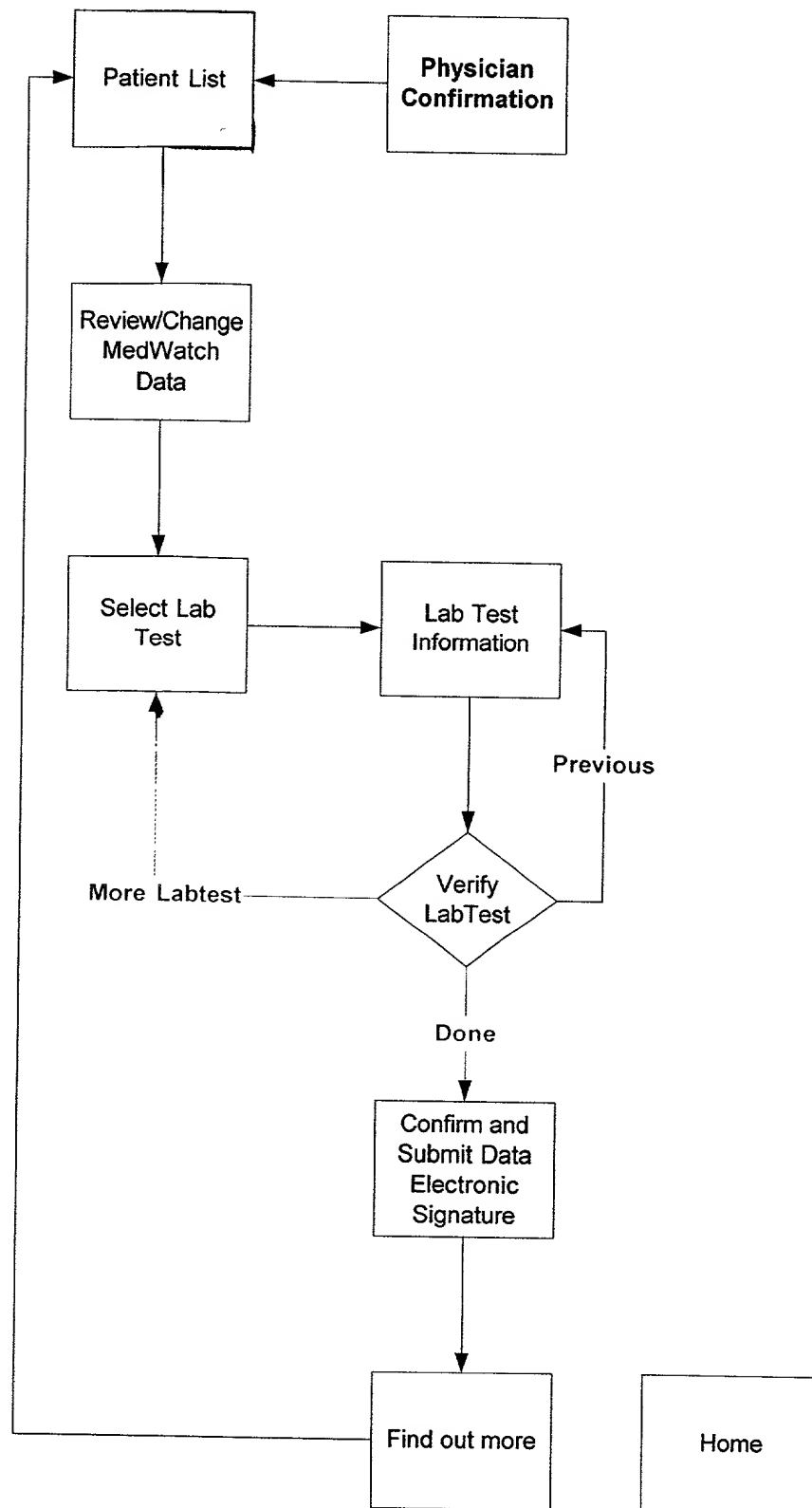
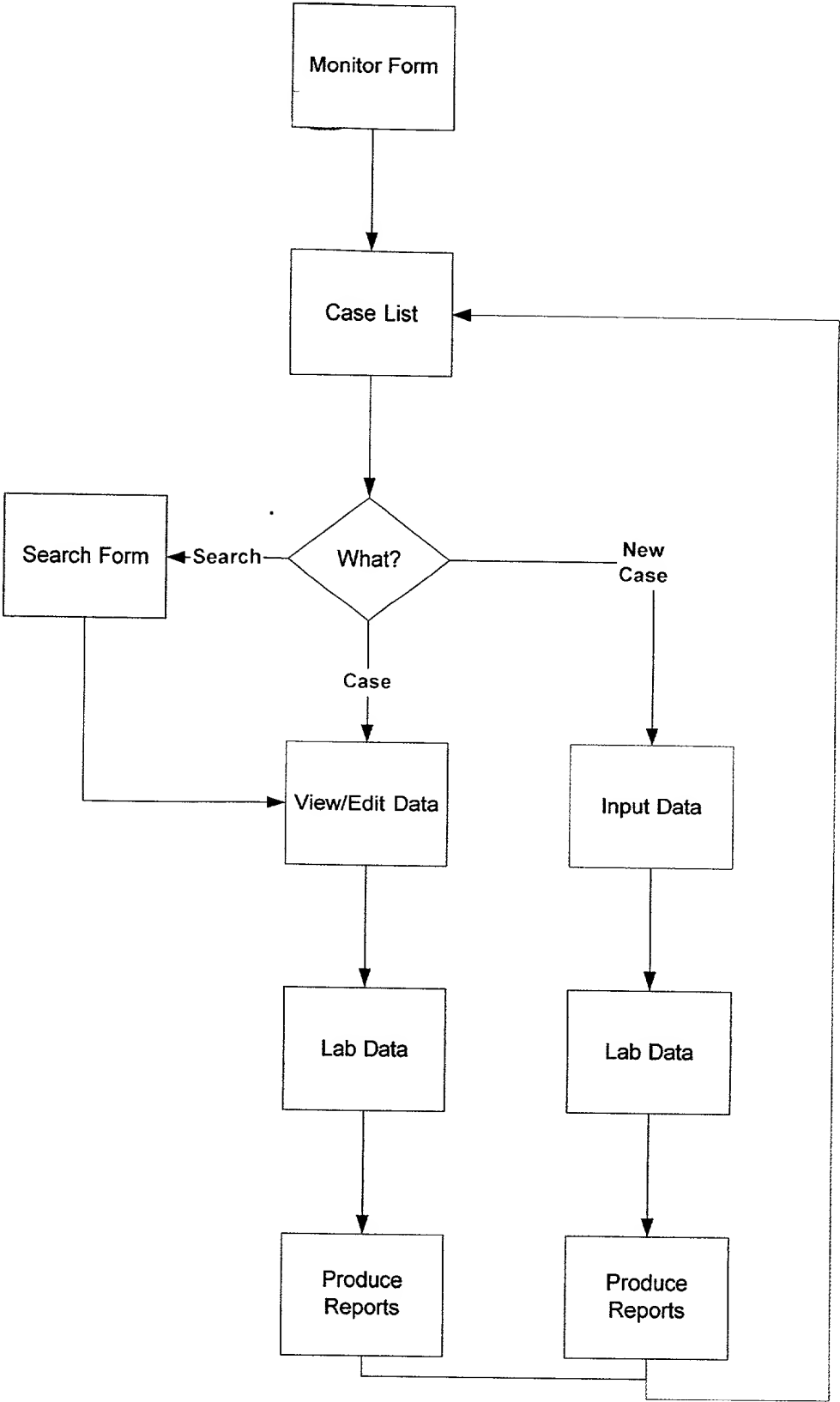


Fig. 3c

Monitor Form



Home

Fig. 3d

Current Side Effects

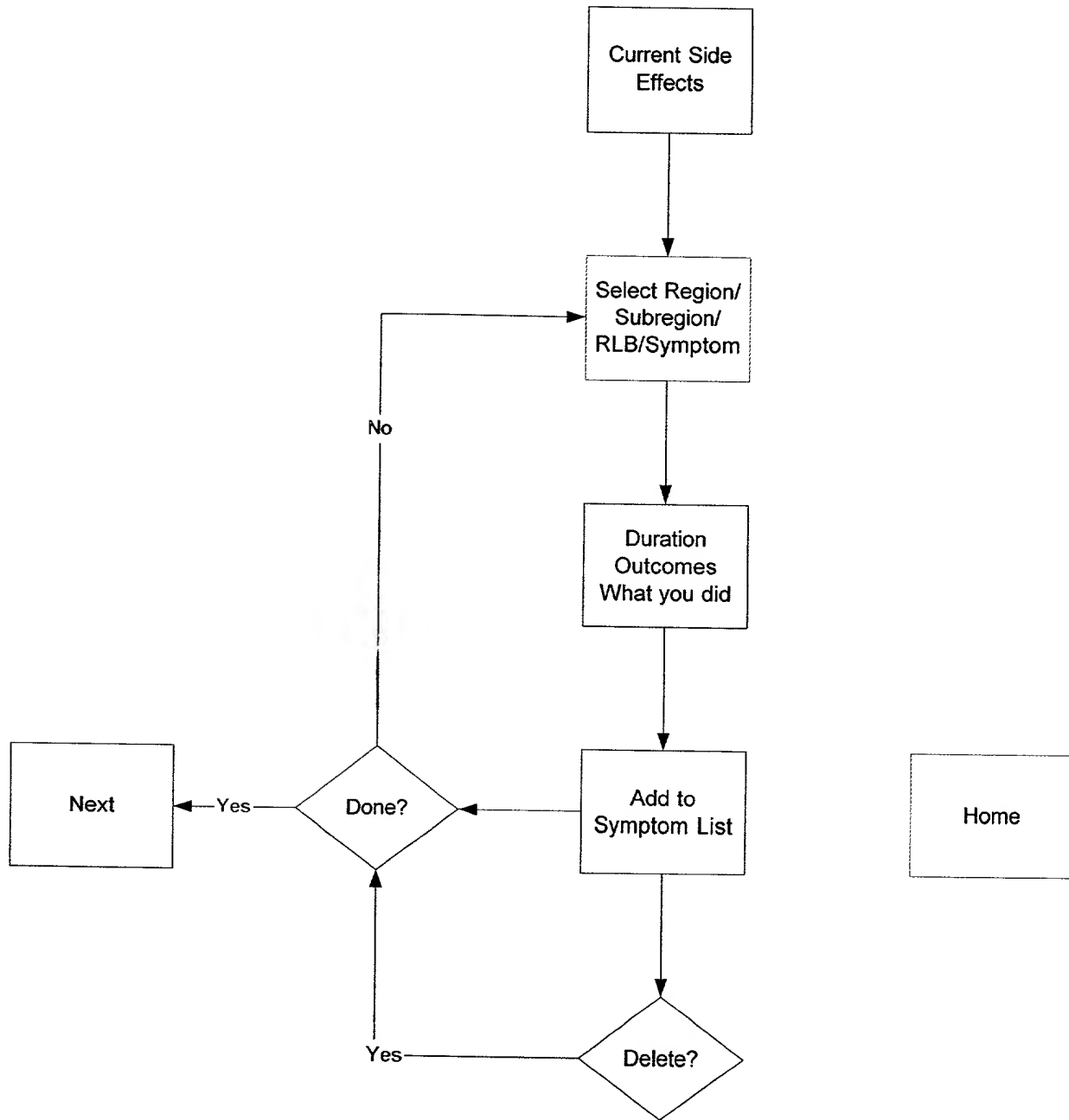


Fig 3e

Current Medication

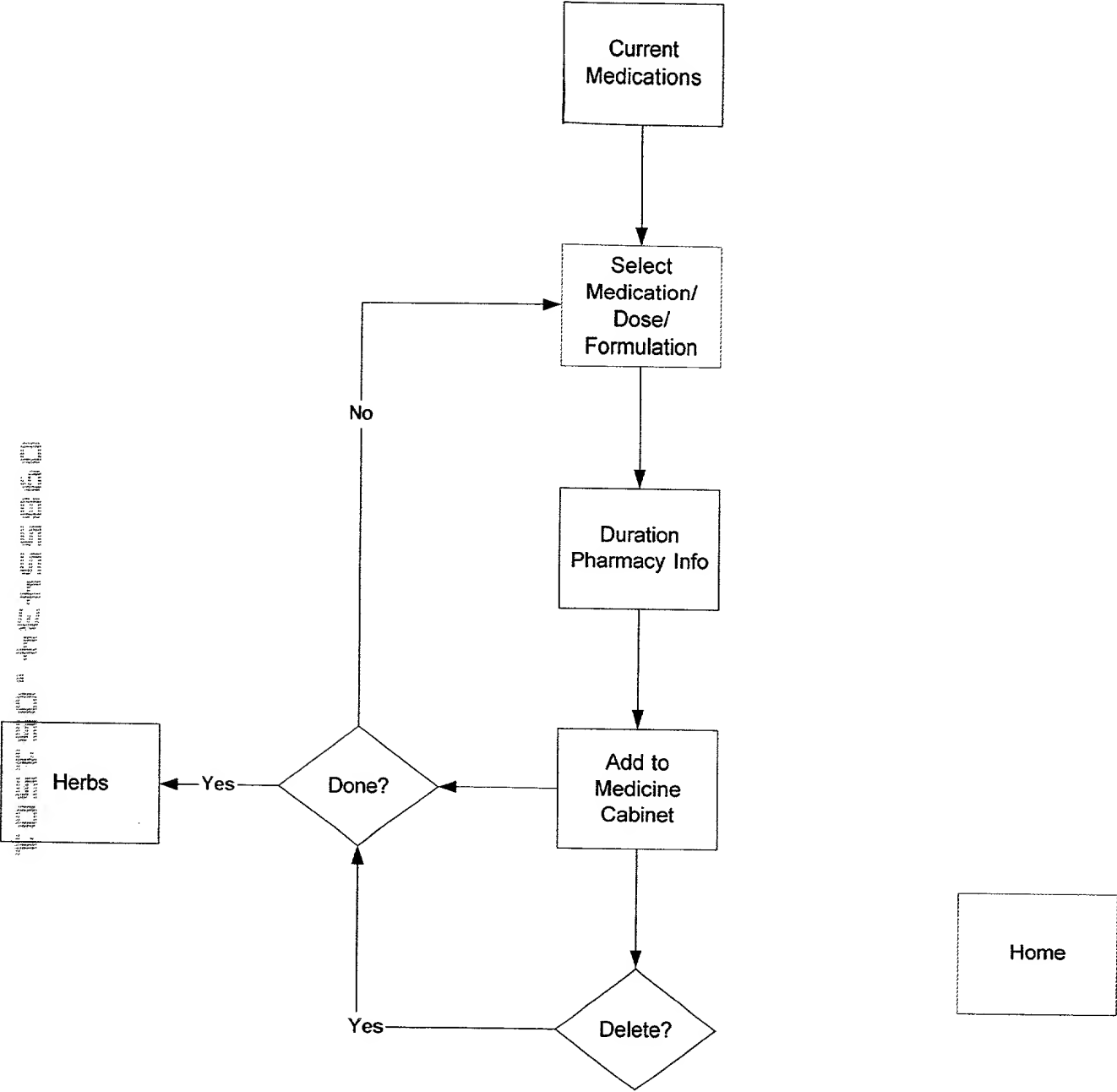


Fig 3A

Herbs and Nutritional Supplements

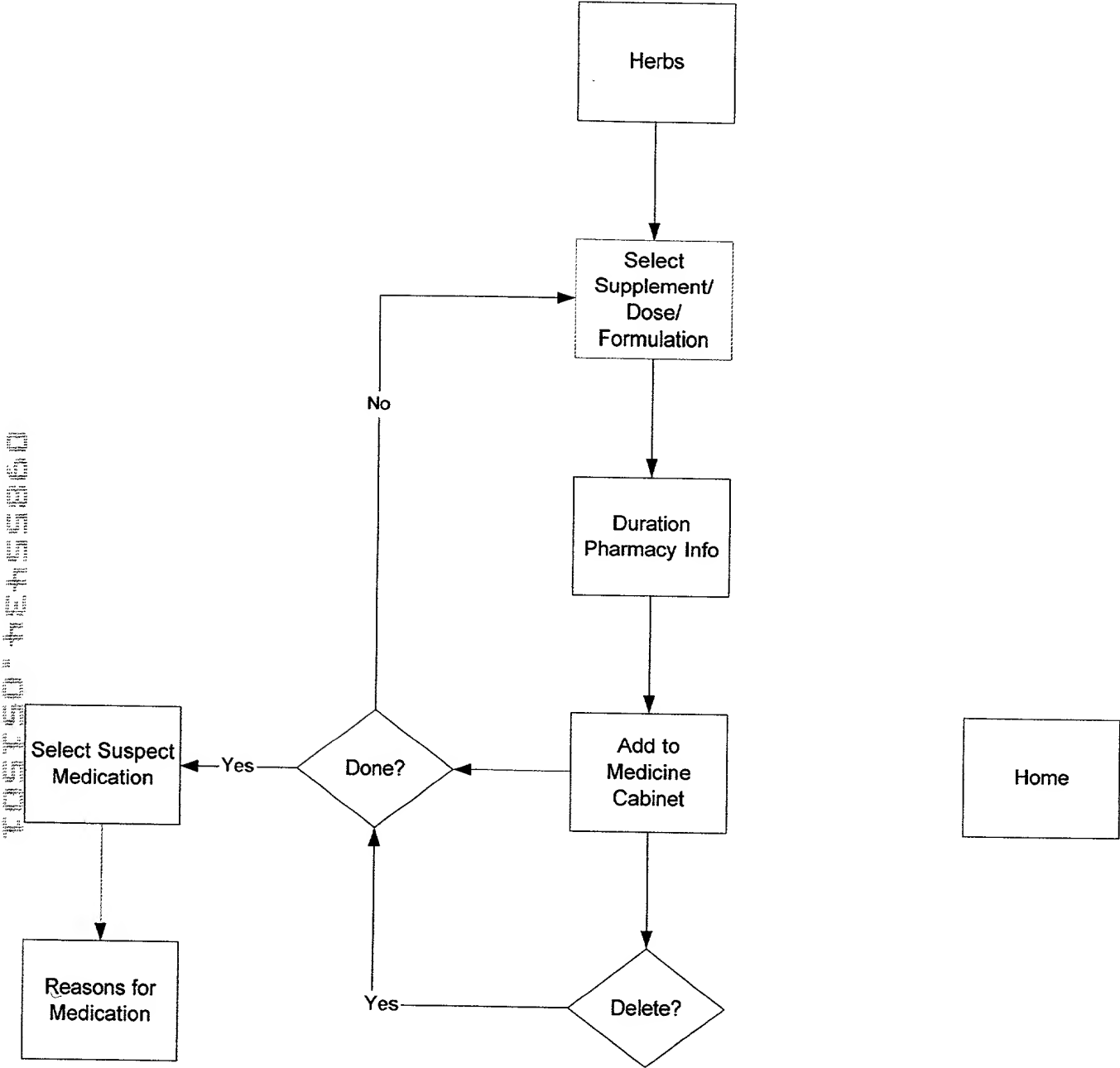


Fig. 39

Reasons for Medication

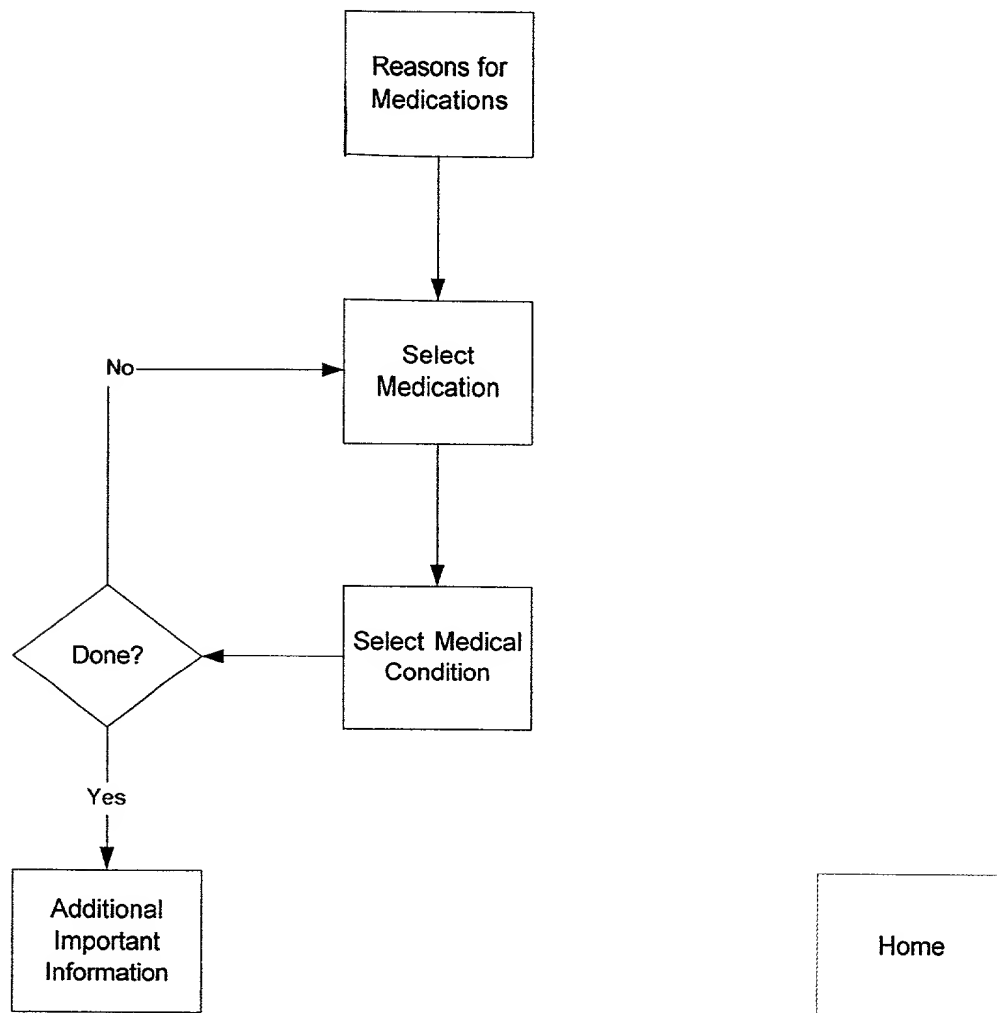
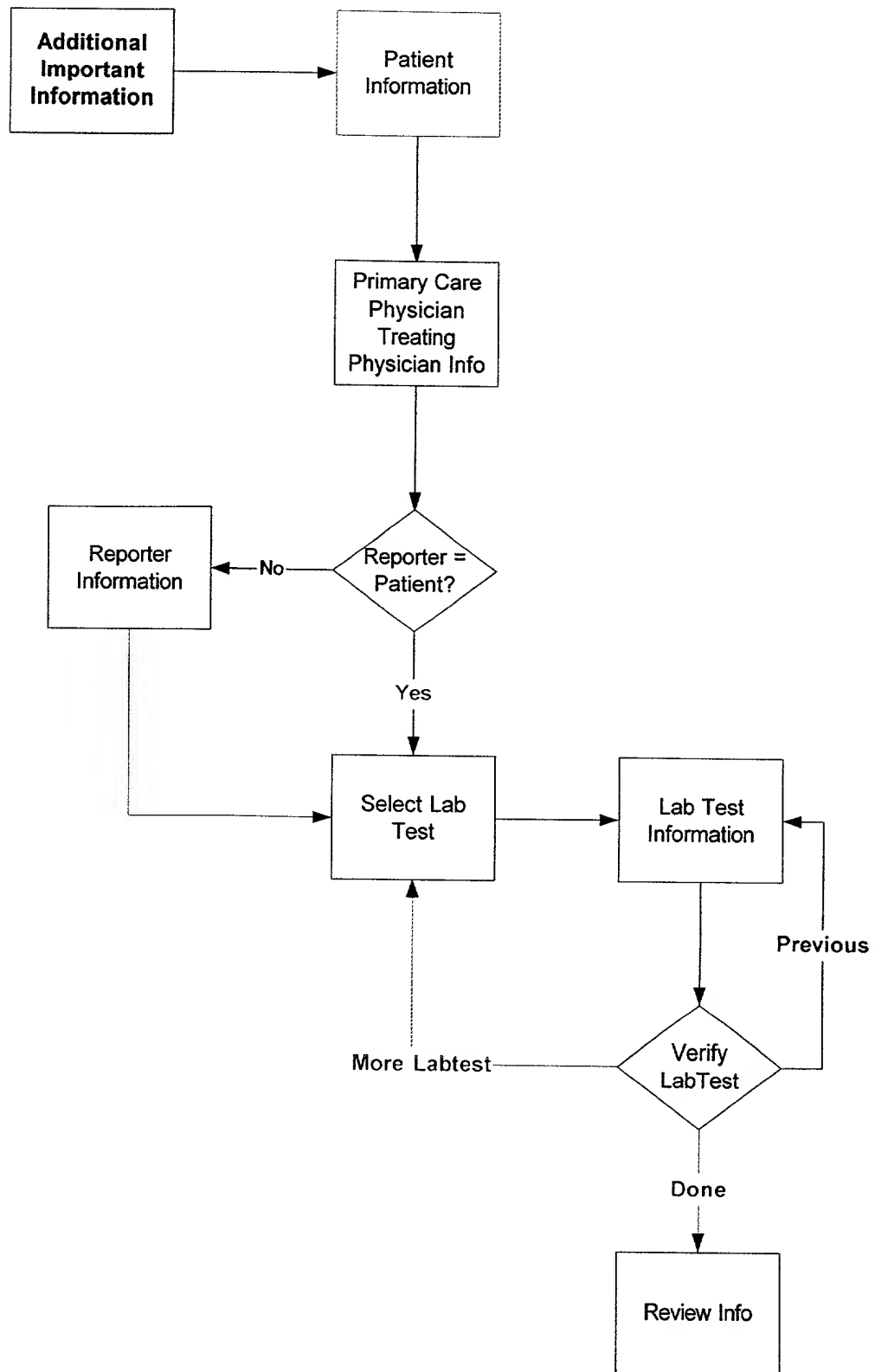


Fig 3h

Additional Important Information



Home

Review Information and Find out More

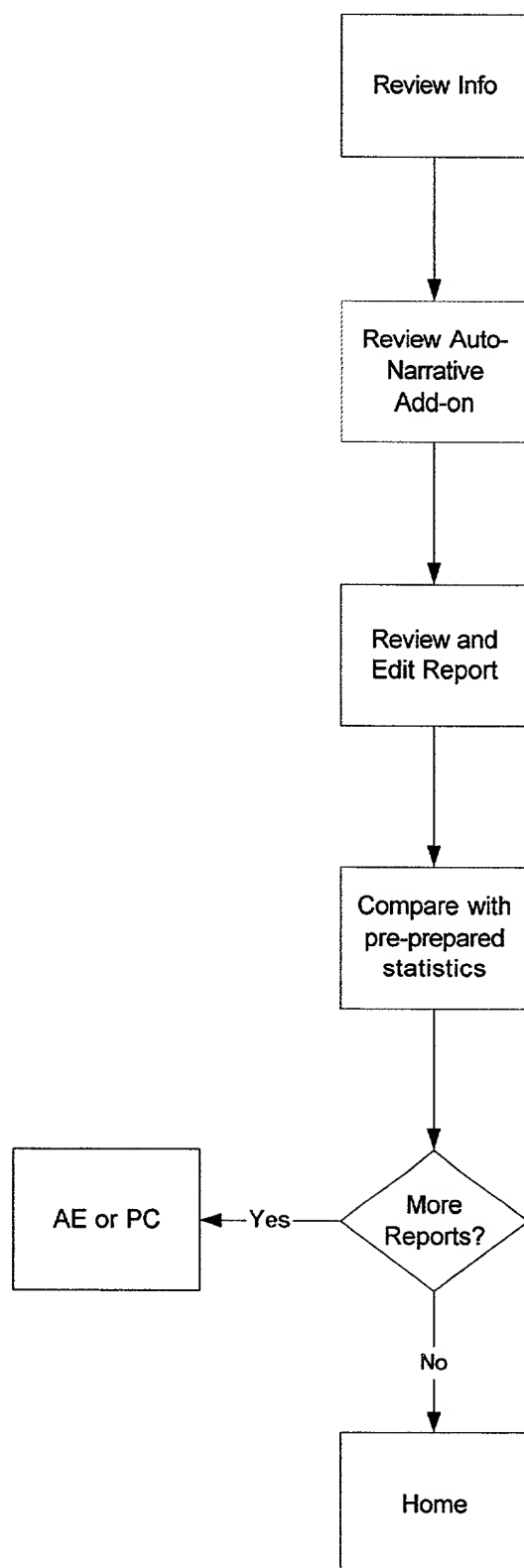


Fig. 30

Product Complaint

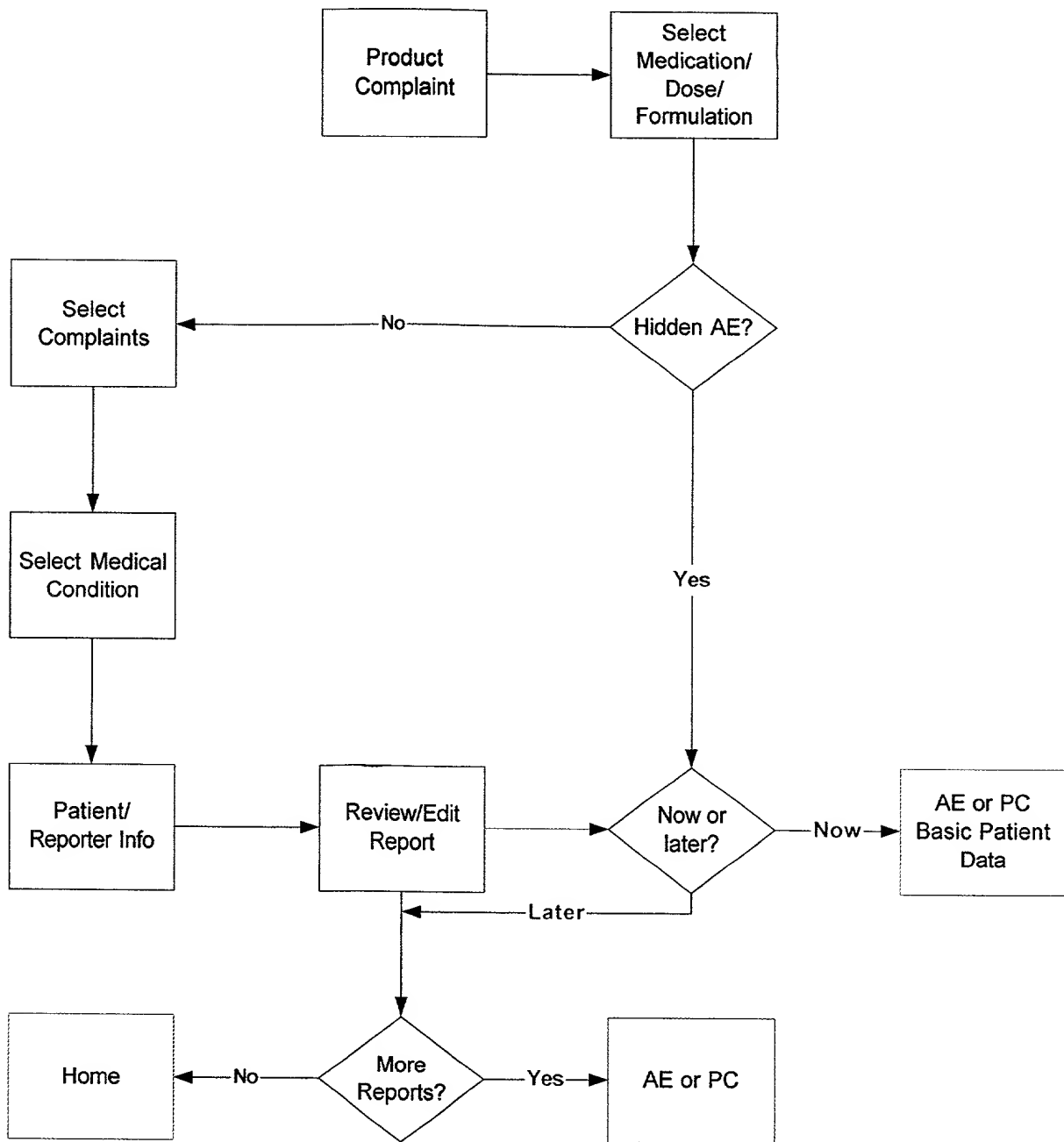


Fig. 3k



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Registration

Informed Consent

In order to complete the report, we may need to contact your physician. Your consent to contact your physician is called informed consent. Only your physician and you will see the information you provide us.

☒ Accept (required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-create it: 1) define a secret question (ex: *What is my favorite football team*) 2) define a secret answer (ex: *the SF 49ers*). Together these will identify you.

For this pilot, type the 8 digit registration code printed on your trial card.

First Name

Last Name

User ID

Password

Password again

Secret Question

Secret Answer

Phone Number

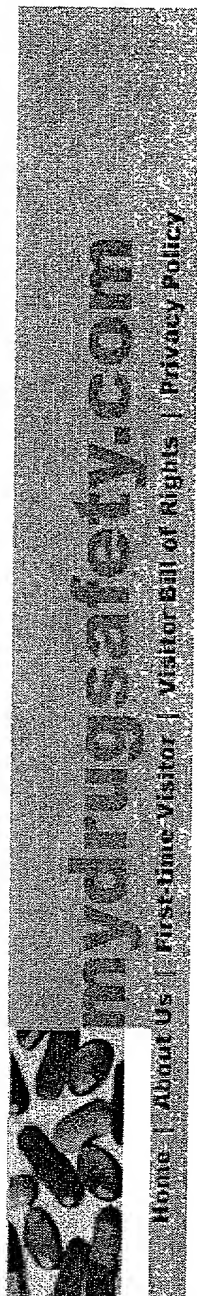
E-mail

1 Getting Started

Login/Registration
Instructions

Who are you

Side Effects and/or
Product Complaints



Welcome to MyDrug Safety


Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.



The  symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

UserID and Password

UserID

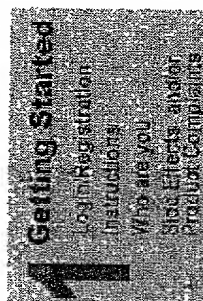
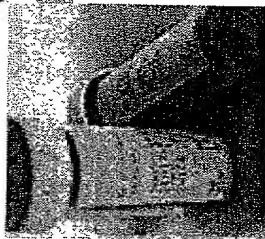
Password

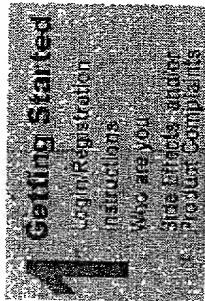
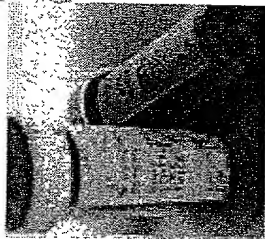
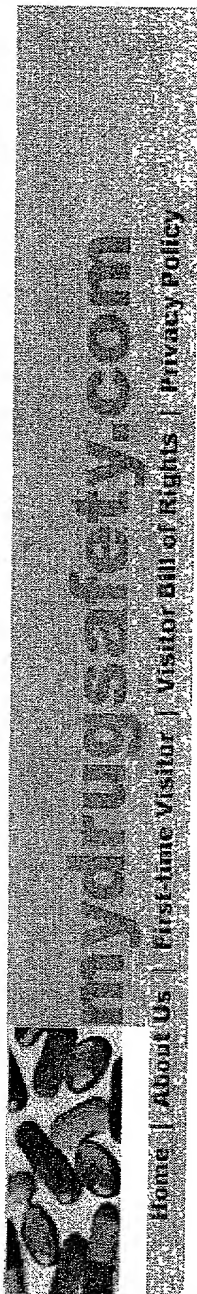
Change your password?

New Password

Repeat Password

Next





Patient-Physician Relationship

The Patient/Physician Relationship

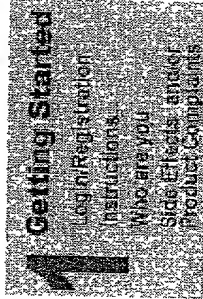
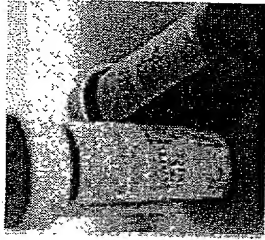


To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on [Registration](#) or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear	Recover
-------	---------

Fig 6



Instructions

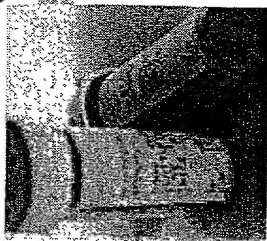
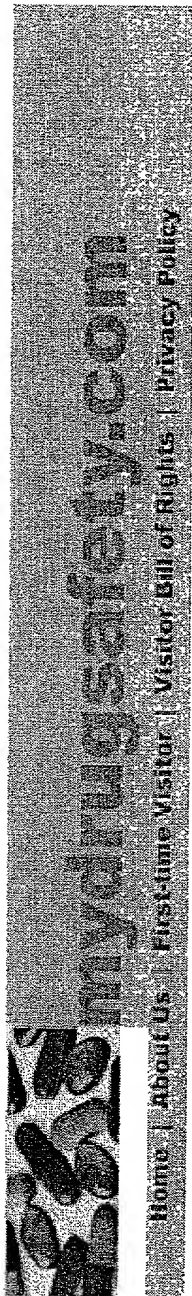
Easy steps to report a Side Effect or Adverse Event

- STEP 1: Side effects or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional important information
- STEP 5: Review your report and find out more

Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for medication
- STEP 3: Additional important information
- STEP 4: Review your report

Next



1 Getting Started
Login/Registration
Instructions
Who are you?
Side Effects, and/or
Product Complaints

Who Are You?



Who Are You?

Family member/spouse

Patient Caretaker

Patient

Pharmaceutical Representative



Someone else? Who?

Previous

Next

Treating physician
---Choose One---

Other Healthcare
Professional
---Choose One---

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Help

{helpscreens}

Figure 8

Adverse Event or Product Complaint?

What Do You Want to Report?

☐ AE

Adverse Reaction or a Side Effect you are having

☐ PC

Complaint about your medication

Family Members Data:

Date of Birth (mm-dd-yyyy)

or Age

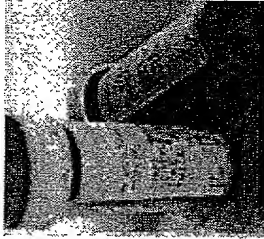
Height feet inches
(ex: 5 feet 2 inches)

Weight lbs

☐ Male ☐ Female

Pregnant ☒ YES

[Next](#)



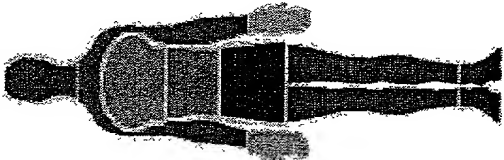
Adverse Event Define a Symptom

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>2</p> <p>To delete a symptom from highlight it and press Delete</p> <p>Only when you have finished describing all your symptoms press Done</p>
<p>Click the region where the symptom occurs.:</p>	<p>REGION Which area?:</p> <ul style="list-style-type: none"> Anus Bladder Buttocks Cervix Groin Labia Minora/Majora Ovaries Rectum Uterus Vagina 	

- 1 Getting Started
- 2 Current Side Effects
 - What Symptom
 - When Started/Ended
 - What Result
 - What You Did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

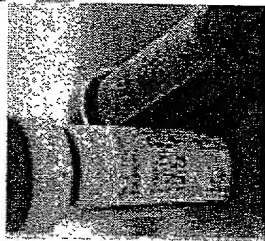


Adverse Event Define a Symptom

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>?</p> <p>To delete a symptom from highlight it and press Delete</p> <p>Only when you have finished describing all your symptoms press Done</p>
<p>Click the region where the symptom occurs.:</p> 	<p>REGION Which area?:</p> <p>Right-Buttocks Left-Buttocks Both-Buttocks</p>	

or

Fig. 10b



1 Getting Started

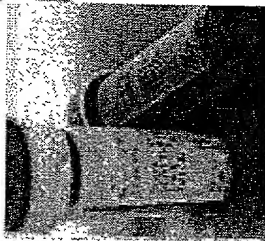
2 Current Side Effects
What Symptoms
When Started/Ended
What Result
What You Did

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More



Adverse Event Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptom occurs.:	REGION Which area?	SYMPTOM What symptom?	DURATION	WHAT YOU DID ABOUT IT
	Buttocks	Hip Pain	When did it start? (mm-dd-yyyy) When did it end? (mm-dd-yyyy) OR How Long did it last? Year <input type="text"/>	<input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="text"/> <input type="checkbox"/> Switched Medication to <input type="text"/> <input type="checkbox"/> Did it help? <input type="checkbox"/> Took Medication again and effect came back <input type="checkbox"/> Took something for it. What? <input type="text"/>

To delete a symptom from highlight it and press **Delete**

Only when you have finished describing all your symptoms press **Done**

- Getting Started
- Current Side Effects
 - What Symptoms
 - When Started/Ended
 - What Result
 - What You Did
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More

Fig. 10c

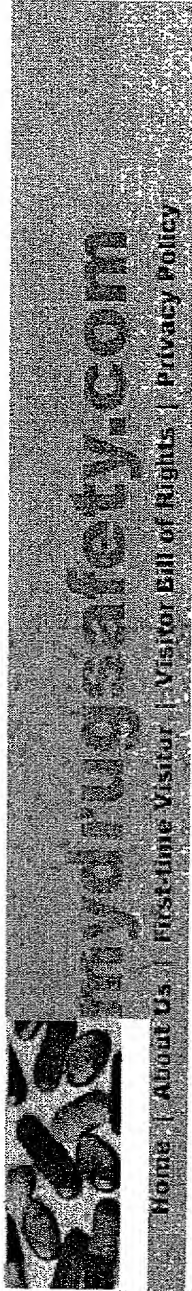
General Body			<div><input type="checkbox"/> Congenital Anomaly</div> <div><input type="checkbox"/> Intervention Needed</div> <div><input type="checkbox"/> Life-Threatening</div> <div><input type="checkbox"/> Died</div> <div><input type="checkbox"/> (mm-day-yyyy)</div> <div><input type="checkbox"/> Other</div>	<div>Did it help? <input type="checkbox"/> YES</div> <div>Did something else</div>
<div>Add Symptom to list</div>				

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Help

{helpscreens}

Fig. 10c



What Medication Are You Taking?

<p>1 Getting Started</p>		<p>2 Current Side Effects</p>		<p>3 Current Medications Medications Herbs & Supplements Suspect Medication</p>		<p>4 Reasons for Medication</p>		<p>5 Additional Important Information</p>		<p>6 Review Info & Find Out More</p>	
<p>Medication: Lamisil Dose: 1 %</p> <p>Formulation: CREAM</p> <p>Frequency: 0 Times a day.</p>						<p>Your Medicine Cabinet ?</p> <div> <p>To delete a medication from the list highlight it and press Delete</p> <p>When your current medication list is complete press Done</p> </div> <p>How long <input type="text"/> Year <input type="text"/></p> <p>Start <input type="text"/> (mm-dd-yyyy) End <input type="text"/> (mm-dd-yyyy)</p> <p>Still on it <input type="checkbox"/> optional info Lot # of drug? if present <input type="text"/></p> <p>What Pharmacy did you purchase it at? <input type="text"/> Name <input type="text"/> Zipcode <input type="text"/></p> <p>Add to Medicine Cabinet</p>					

Figure 11

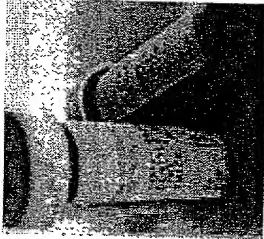


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What Medication Are You Taking? Suspect Medication

Please select the medication(s) that you think may have caused the event.		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
Previous		Next



1 Getting Started

2 Current Side Effects

3 Current Medications
Medications
Herbs & Supplements
Suspect Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info. & Find Out More

Figure 12



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What Medication Are You Taking?

Herbs or Nutritional Supplements



1 Getting Started

2 Current Side Effects

3 Current Medications
Medications
Herbs & Supplements
Problem Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

<p>Tell us what herbs or other supplements you are taking.</p> <p>Click letter to choose from list.</p> <p> A B C D E F G H I J K L M N O P Q R S T U V W X Y Z </p> <p>Pick one: <input type="text"/> select a medication</p> <p>Not on the list? Enter below <input type="text"/></p> <p>What Dose <input type="text"/></p> <p>Times a day <input type="text"/></p> <p>What Formulation? <input type="text"/></p>	<p>?</p> <p>Your Current Herbs -----Your Current Medications----- &medicine1 &medicine1</p> <p>How long <input type="text"/> days <input type="text"/></p> <p> Start <input type="text"/> mm-dd-yy End <input type="text"/> mm-dd-yy <input type="checkbox"/> Still on it </p> <p>---optional info--- Lot # of supplement? if present <input type="text"/> What Pharmacy did you purchase it at? <input type="text"/> name <input type="text"/> zipcode <input type="text"/> </p> <p> <input type="button" value="Add to Medicine Cabinet"/> <input type="button" value="Delete"/> <input type="button" value="Done"/> </p> <p> Need To delete a medication from your current list? highlight it and press When your current medication list is complete press </p>
--	--

Fig. 13

Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear. Select the appropriate one. Repeat for each medicine in the list. **2**

Your Medication List			Medical Condition
Medication	Formulation	Dose	
Lamisil	CREAM	1 %	<div> <div>Frequency (Times a Day)</div> <div>4</div> </div> <div> <div> <div>-----select only one-----</div> <div>Not on the list? ...Enter below</div> </div> </div>

Previous Next

- 1

Getting Started
- 2

Current Side Effects
- 3

Current Medications
- 4

Reasons for Medication
- 5

Additional Important Information

[Patient Information](#)
[Physician Information](#)
[Lab Test Results](#)
- 6

Review Info & Find Out More

Adverse Event

Lab Results

?

Tell us what tests were done

Click letter to choose from list.

A

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

Q

R

S

T

U

V

W

X

Y

Z

Then Select the appropriate test and method for the specimen, enter results. Standard Values for the test will be presented with an indicator for whehter the patient values are within range or out of range.

Test	Specimen	Method	Min - Max	Test Value Measurement Time & Date	Status of Test
Albumin	Serum	Colimetry	3.5 - 5.0 g/dl	<div> <div></div> <div>g/dl</div> <div></div> <div>time</div> <div></div> </div> <div> <div>dd</div> <div>mm</div> <div>year</div> </div>	●
Aldolase				<div> <div></div> <div>g/dl</div> <div></div> <div>time</div> <div></div> </div> <div> <div>multiple test values at this date?</div> <div> <div>dd</div> <div>mm</div> <div>year</div> </div> </div>	●
Aldosterone				<div> <div></div> <div>g/dl</div> <div></div> <div>time</div> <div></div> </div> <div> <div>multiple test values at this date?</div> <div> <div>dd</div> <div>mm</div> <div>year</div> </div> </div>	▲
Alkaline				<div> <div></div> <div>g/dl</div> <div></div> <div>time</div> <div></div> </div> <div> <div>multiple test values at this date?</div> <div> <div>dd</div> <div>mm</div> <div>year</div> </div> </div>	▼
Phosphatase				<div> <div></div> <div>g/dl</div> <div></div> <div>time</div> <div></div> </div> <div> <div>multiple test values at this date?</div> <div> <div>dd</div> <div>mm</div> <div>year</div> </div> </div>	●

Next

Tig 14A

Adverse Event Product Complaint

Check your record

This Report

A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 & CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].

The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablaba

Previous

Next

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Review Narrative

Review Your Info

Other Similar Reports to the FDA



Review Your & Who Record Summary Report pat1 patlast

Review and edit your report,



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More
Review Narrative
Review Your Info
Other Similar Reports to the FDA

Report is complete

Type over text to edit and only when complete press

A. Patient Information

Patient Name
Date of Birth
Age at Event
Gender
Pregnant?
Weight
Height

pat1 patlast
06-16-70
-30
Male
Yes
110
5 feet 6 inches
(ex: 5 feet 2 inches)

B. Adverse Event Results

Died On (mm-day-yyyy)
Hospitalized Less than 24 Hrs
Hospitalized over 24 Hrs
Disability
Congenital Anomaly
Intervention Needed
Life Threatening
Other
Date of Event (mm-dd-yyyy)
Date of Report (mm-dd-yyyy)

Description

Event Abated? ☐ Yes ☐ No ☐ Unknown
Event Reappeared? ☐ Yes ☐ No ☐ Unknown

C. Suspect Medications

Drug Name	Dose	Therapy Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration: 1 Year	Disease 2

D. Concomitant Medication

Drug Name	Dose	Therapy Dates/Duration	Reason
-----------	------	------------------------	--------

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Help

{helpscreens}

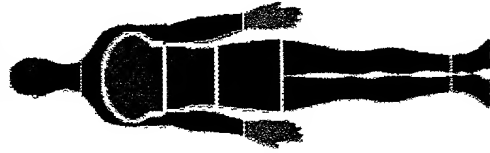
Fig. 16



Arzneimittel-Nebenwirkungen Definieren Sie Das Symptom

Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu beschreiben. Klicken Sie bitte eine Körperebene an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.

Klicken Sie bitte die Region, in der Ihr Symptom sich äußert



KOPF
Wählen Sie die Region?:

SYMPTOM
Ihr Symptom

AUGEN

VERENGTE
PUPILLEN

DAUER

Beginn des Symptoms
mm-dd-yy

Ende des Symptoms mm-dd-yy

Wie lange dauerte es?

Tage

Besteht das Symptom immer noch?

☐ JA

WAS UNTERNAHMEN SIE DAGEGEN?

☐ Nichts

☐ Konsultierte einen Arzt

☐ Stoppte die Medikamenten-Einnahme

Reduzierte die Medikamenten-Dosis auf

☐ Wechselte das Medikament auf

Half es? ☐ JA

☐ Nahm das Medikament wieder und der Effekt erschien wieder

AUSWIRKUNG DES SYMPTOMS

Hatte das Symptom direkte medizinische Auswirkungen, wie

1 Start

Login/Registrierung
Benutzeranmeldung
Wer sind Sie?
Arzneimittel
Nebenwirkung oder
Beschwerden über das
Arzneimittel

2 Arzneimittel-Nebenwirkung

Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Gegenreaktionen

3 Ihre Medikamente

Medikamente
Andere Medikamente
Heilkräuter & Vitamine

4 Weshalb nehmen Sie?

Fig. 16a

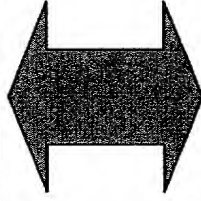
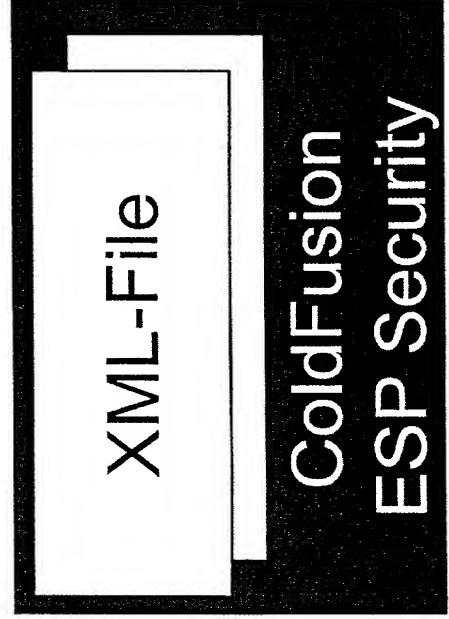
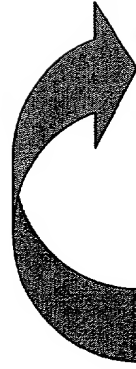
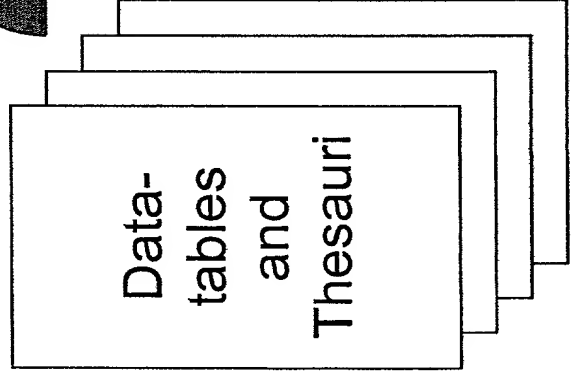
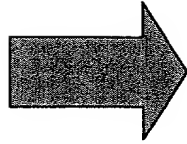
5 **Zusätzliche
Informationen**
Patienten-Daten
Arzte-Daten

				Hospitalisierung unter 24 Std	<input type="checkbox"/> Nahm ein Gegenmittel. Was?
					SYMPTOM ZUR LISTE HINZUFÜGEN

6 **Bestätigen
Sie Ihre Daten**
Ihr generierter Bericht
Alle Ihre Daten
Vergleich mit anderen
Berichten der FDA

Fig. 1ba

Objectives
Desired
Outcome



HTML-Interface

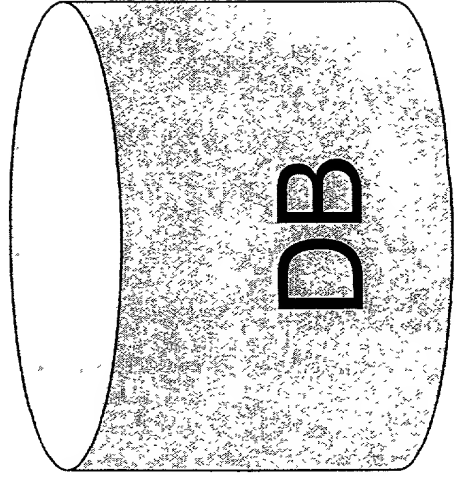
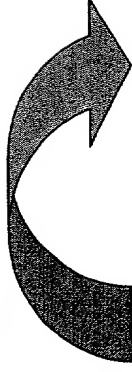


Fig. 17

Cognitive function		Personality		Social functioning		Quality of life	
Pre-AD	AD	Pre-AD	AD	Pre-AD	AD	Pre-AD	AD
100	95	100	95	100	95	100	95
95	90	95	90	95	90	95	90
90	85	90	85	90	85	90	85
85	80	85	80	85	80	85	80
80	75	80	75	80	75	80	75
75	70	75	70	75	70	75	70
70	65	70	65	70	65	70	65
65	60	65	60	65	60	65	60
60	55	60	55	60	55	60	55
55	50	55	50	55	50	55	50
50	45	50	45	50	45	50	45
45	40	45	40	45	40	45	40
40	35	40	35	40	35	40	35
35	30	35	30	35	30	35	30
30	25	30	25	30	25	30	25
25	20	25	20	25	20	25	20
20	15	20	15	20	15	20	15
15	10	15	10	15	10	15	10
10	5	10	5	10	5	10	5
5	0	5	0	5	0	5	0
0	-5	0	-5	0	-5	0	-5
-5	-10	-5	-10	-5	-10	-5	-10
-10	-15	-10	-15	-10	-15	-10	-15
-15	-20	-15	-20	-15	-20	-15	-20
-20	-25	-20	-25	-20	-25	-20	-25
-25	-30	-25	-30	-25	-30	-25	-30
-30	-35	-30	-35	-30	-35	-30	-35
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-40	-45	-40	-45	-40	-45	-40	-45
-45	-50	-45	-50	-45	-50	-45	-50
-50	-55	-50	-55	-50	-55	-50	-55
-55	-60	-55	-60	-55	-60	-55	-60
-60	-65	-60	-65	-60	-65	-60	-65
-65	-70	-65	-70	-65	-70	-65	-70
-70	-75	-70	-75	-70	-75	-70	-75
-75	-80	-75	-80	-75	-80	-75	-80
-80	-85	-80	-85	-80	-85	-80	-85
-85	-90	-85	-90	-85	-90	-85	-90
-90	-95	-90	-95	-90	-95	-90	-95
-95	-100	-95	-100	-95	-100	-95	-100
-100	-105	-100	-105	-100	-105	-100	-105
-105	-110	-105	-110	-105	-110	-105	-110
-110	-115	-110	-115	-110	-115	-110	-115
-115	-120	-115	-120	-115	-120	-115	-120
-120	-125	-120	-125	-120	-125	-120	-125
-125	-130	-125	-130	-125	-130	-125	-130
-130	-135	-130	-135	-130	-135	-130	-135
-135	-140	-135	-140	-135	-140	-135	-140
-140	-145	-140	-145	-140	-145	-140	-145
-145	-150	-145	-150	-145	-150	-145	-150
-150	-155	-150	-155	-150	-155	-150	-155
-155	-160	-155	-160	-155	-160	-155	-160
-160	-165	-160	-165	-160	-165	-160	-165
-165	-170	-165	-170	-165	-170	-165	-170
-170	-175	-170					

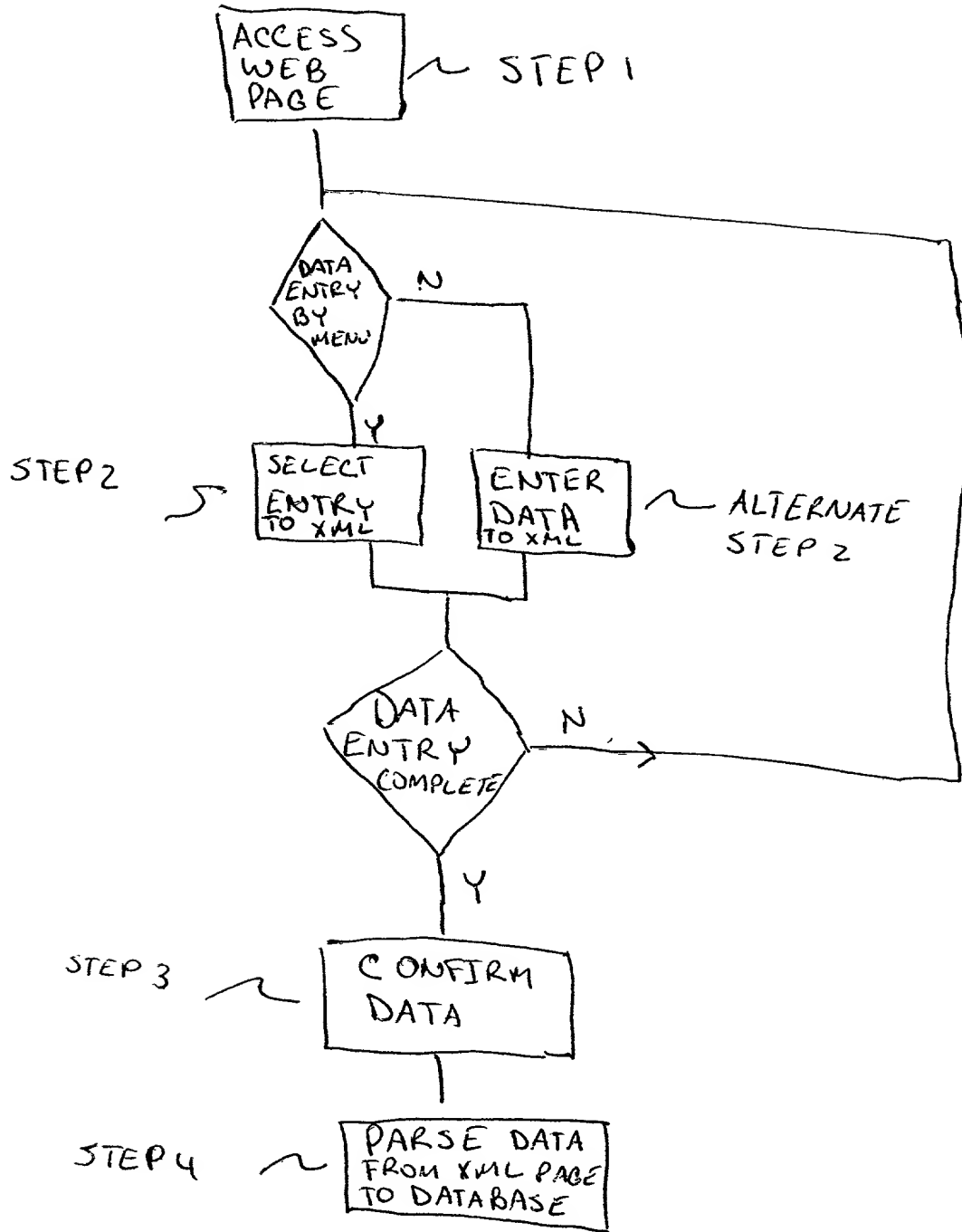


Figure 18